PROPER USE OF THE METERED-DOSE INHALER IN CHILDREN UTILIZING A ONE-ON-ONE TEACHING PLAN

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PROPER USE OF THE METERED-DOSE INHALER IN CHILDREN UTILIZING A ONE-ON-ONE TEACHING PLAN

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ABSTRACT

The regular use of inhaled anti-inflammatory agents with inhaled *B*-agonists for rescue is considered the mainstay of therapy for long-term asthma. The success of metered-dose inhalers (MDIs) in treating lung disease depends chiefly on inhaler technique, patient compliance, and appropriate dosage. A pilot study to examine the effectiveness of a teaching tool for proper MDI use in a population whose age ranged from 8 to 12 years was conducted in a military pediatric asthma clinic. A pretest-posttest quasi-experimental design was used to determine if a one-on-one teaching plan with bronchodilator inhalers would improve use of MDI technique and thus improve pulmonary function in this young population. The eight question inhaler skills checklist tool developed by the American Institutes for Research was used to measure each child's proper use of the MDI. Only children presently prescribed a bronchodilator MDI were accepted into the study. Pretest-posttest measures included pulmonary function tests (PFTs) and the metered-dose inhaler checklist (MDIC). On the first visit the child was pretested for baseline PFT and then evaluated for proper MDI use with the usual prescribed two puffs of albuterol. A PFT was again conducted 10 minutes after the MDI use. The teaching plan was then implemented. Posttests using the two same measures (MDIC & PFT) were then completed at least 20 minutes after the child had self-administered the first dose of bronchodilator. The second visit was conducted after a one to two week lapse in time from the first visit and in the same manner as the first, but without the teaching intervention. Descriptive data on the teaching tool were obtained in order to find specific areas of technique that most hamper proper use of the MDI by this group of children. All children improved at least 25% on MDI use in this pilot study. Matched t-test were conducted on the pretest and posttest pulmonary function test results for the group. Statistical significant results were not obtained at the 0.05 level of significance. Contributing factors could be the small sample size and the lack of a compromised

baseline pulmonary status (83% of the subjects had greater than 80% function). In order for there to be improvement in pulmonary function, the subject's status must warrant a need for bronchodilation MDI use. Recommendation for further study would be a larger sample size and for the subjects to have a compromized pulmonary status requiring the need for MDI use.

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by

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DEDICATION

To my three daughters, and husband, I know the last twenty months have been a time of character building for each of us. I hope the memories that linger are those funny, crazy times.

You girls can think of it as a time of watching your Mom struggling to meet deadlines; a time of having your room cleaner than mine; and a time of purchasing a second computer because your Mom kept monopolizing the one.

We all have fond memories of study times with Kate Fuller, Michelle Lavey, and her girls that turned into overnight sleep-overs with pizza, movies, dancing, and Kate's fudge, and waking up to immobile cars the next morning due to the ice and snow.

We have lasting memories of natures fireworks in our Nation's Capitol and later the same day, with the Washington Monument as the backdrop, our very own fireworks show (with half a million others), and then later that night piling onto the Metro with friends.

To watch my 92 year old father-in-law in the living room dancing with all of us and friends, is one memory I won't forget. I could see the joy and wisdom through all those wrinkles on his face, but he convinced me long ago that he knows what is important in life and I thank him for sharing his wisdom with us.

My husband, Dudley Bourne, continues to bring out the funny side of any difficult situation and makes me laugh. Thanks for being that steadfast, unfailing person in my life.

To each of you, I thank you for your support through these twenty months to accomplish a personal goal of mine. I dedicate this work to you and to your goals in life.

ACKNOWLEDGMENT

Many people with vision worked hard for years in order for this Graduate School of Nursing to become a reality. I thank now retired U. S. Air Force General Turner for her foresight and her dedication to nursing and health care. Doors of knowledge and opportunity have been opened to ten USAF nurses that will graduate this May and to more in the future.

As a novice in research, my first time experience was a positive one, and I realize it was not an accident or streak of good luck. To Dr. Barbara Sylvia, I am grateful for your guidance, knowledge, and support. I am in dismay of your unselfish hours spent not only on my work but others as well. You're kind, soft spoken voice never faltered even when deadlines were near. Somewhere in the process, I became immersed in the research and surprisingly interested and intrigued by it. Thank you for that gift.

To Gloria Deniz, Lt. Col. (USAF Ret.), I thank you for sharing your expertise in asthma but even more your expertise in dealing with children. Your insight into interacting with children could never be totally attained in a book. It takes a mentor to watch and be immersed in that role.

I thank Dr. John McQueston, CDR, USN, for sharing his enthusiasm for providing quality health care to children with asthma. The invaluable lessons learned will not stop here with research but will serve me clinically as well. I felt welcome at Bethesda Navy Medical Center from the start. Thank you for your valuable time teaching me, introducing me to people, and sharing your patients.

I especially thank Gilbert Crowder, HM2, USN, Certified Respiratory Technician, who gave of his time on duty and also his own time on weekends to conduct this research. Your professionalism did not go unnoticed. I wish you the best in your career.

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CHAPTER ONE

Introduction

Background

Asthma is the most common chronic lung disorder of children, the most frequent cause of medical hospital admissions for children, and the most frequent reason given for school absenteeism in the United States (American Board of Pediatrics, 1992; Dershewitz, 1993). Asthma is consistently listed as affecting an estimated 10.3 million people in the United States; 4 million of these are children (National Asthma Education Program, 1991). In 1988, 4,530 people died from asthma in the United States (Janson-Bjerklie, 1992; Reed & Bernstein, 1986). It is not a problem exclusive to the U.S. Rather, it is estimated that between 3% and 6% of the population in most industrialized countries have asthma. The incidence in childhood is estimated as high as one in every five in the U.S. and higher among boys than girls. The incidence after puberty is similar in each gender (Anderson, 1991; Schaffer, 1991).

Current treatment for asthma emphasizes the role of self-administered inhalation therapy (National Asthma Education Program, 1991). The metered-dose inhaler (MDI) facilitates the distribution of medication into the tracheobronchial tree by aerosolization and has been recognized as an efficient way to treat lung diseases. The regular use of inhaled anti-inflammatory agents with inhaled *B*-agonists for rescue is now considered the mainstay of therapy for the person with long-term asthma (Hanania, Wittman, Kesten, and Chapman, 1994). The MDI is the most favored form of aerosol therapy because of its precision in dosing, small size, portability, time savings, and lower cost. The success of MDIs in treating lung disease depends chiefly on inhaler technique, patient compliance, and appropriate dosage (Reardon & Bragdon, 1993). Substantial research studies on proper MDI use have been conducted on the adult population (Larsen, Hahn, Ekhom, & Wick, 1994; Reardon & Bragdon, 1993; Thompson, Irvine, Grathwohl, & Roth, 1994). Studies have shown that only 45% to 50% of adult asthma patients utilizing MDI in their

treatment plan use it correctly (Lindgren, Blake, & Larrson, 1987). No research data were found on MDI use specifically in children. MDIs are prescribed to children as well as adults (National Asthma Education Program, 1991). It is assumed that, at best, children would achieve no better results than adults aged 20-60 years of age, and more realistically would probably achieve less optimal result.

At each stage of development, a child must accomplish certain tasks of cognition and social and emotional development in order to advance to the next stage. Chronic illness can interfere with the child's development by delaying or interrupting these sequences (Carlswell et al., 1990). How the child has responded in the past to the effects of asthma and how he/she is maturing will effect the way in which he/she will take responsibility for maintaining self-care. The fact that children are individuals and will react differently to their special needs must be considered.

Chronic illness in the adolescent adds other dimensions to management. The adolescent is at a time of development and maturing; a time for experimenting; and a time of separating from the parent in order to become independent. Some adolescents behave like prepubescent children and others behave as adults. Most teenagers are insecure in relationships with others, overly concerned about their body images, and strongly influenced by their peers. Adolescents with an "invisible" chronic illness may have stress and adaptive problems. They have limits and restrictions caused by asthma even though they usually appear normal. Thus, they cannot always behave like their peers (Dershewitz, 1994).

The scope of the problem is further complicated in the asthmatic child who changes residential locations through childhood. The child of an active duty military member experiences such a life. A change in primary provider may be of some concern, but probably the change in friendships and schools are of greater concern to the child. The number of moves for each family varies. Even the child who moves infrequently will have a change in provider, due to frequent moves of military providers. Because of the

frequent change in health care providers, there is a likelihood of decreased consistency in maintenance education, leading to confusion. The need for consistency in all asthma education is particularly important in the military setting due to these added factors. As pointed out, studies of the adult population have shown that only 45% to 50% of adult asthma patients utilize the MDI correctly. It is assumed the childhood population of asthma patients utilizing the MDI is at best equal to this percentage. Many health professionals are unfamiliar with the practical aspects of MDI use. If they give instructions at all, they are often vague and inaccurate (Reardon & Bragdon, 1993). Providers that are aware of difficulties in MDI use specific to children can be more effective in teaching MDI technique to asthmatic children. This study deals with the proper use of the MDI by children from 8 years to 12 years of age in a military setting.

Purpose

The main purposes of this research study are:

1. To examine the current technique of metered-dose inhaler usage in children 8 to 12 years of age in a military facility.

2. To identify specific problems of metered-dose inhaler technique in children.

3. To measure the effectiveness of a one-on-one teaching plan to improve metered-dose inhaler technique use for those children who demonstrate incorrect MDI technique.

Hypotheses

The hypotheses are:

1. Improved metered-dose inhaler technique will be obtained through a one-on-one individualized teaching plan.

2. Pulmonary function results will improve with improved metered-dose use technique.

Conceptual Framework

In order to obtain mastery of the inhaler technique, each child would have to become independent or a parent or guardian would have to become responsible for the administration of the MDI. Use of Orem's concepts of self-care in the nursing process assists the nurse (or provider) in focusing on patient education. Self-Care is defined by Orem (1991) as "the practice of activities that individuals personally initiate and perform on their own behalf in maintaining life, health and well being". Children begin to take responsibility for their self-care at different ages but overall, according to Piaget, the ability to grasp concepts (but not abstractions) occurs in the range of 7 to 11 years of age. The ability to make abstractions and analyze an idea from several viewpoints (formal operations) begins to occur around 12 years of age (Lewis, 1982; Wadsworth, 1979). Both occur at different degrees in different individuals (maturation). "Self-care is behavior that evolves through a combination of social and cognitive experiences and is learned through one's interpersonal relationships, communication, and culture" (Joseph, 1980, p. 132). The role of the nurse (or provider) is to facilitate and increase the self-care abilities of the patient. Knowledge, skills, attitudes, beliefs, values, and motivation all are factors that affect the performance. Nursing intervention focuses on teaching as a method for increasing the self-care of the patient. A performance criteria to evaluate the outcome of the nursing system in relation to changes in the patient's self-care agency and self-care behavior is needed to justify the teaching technique or tool. The inhaler skills checklist (Appendix A) will serve that purpose in this study.

At what age children begin to independently use their MDI has not been studied. Medications prescribed for MDI use are generally not prescribed for children under six years of age due to coordination difficulties and the time involved in teaching the proper use of the MDI. Some children over six years of age may still require help from an adult to assist with the MDI. Children require varying degrees of assistance with self-care activities. According to Orem's self-care model, the parent may function as substitute self-

care agent in providing care. The role should change gradually from doing to supporting as the child advances in age and takes more responsibility for care (Facteau, 1980).

Definitions of Terms

Asthma--

A chronic respiratory disease characterized by smooth-muscle constriction of the airway that is reversible (but not completely in all patients), bronchial hyper-responsiveness, and an ongoing inflammatory process (American Board of Pediatrics 1992; Janson-Bjerklie, 1993; National Asthma Education Program, 1991; Reinke & Hoffman, 1992; Schaffer, 1991). Although the cause is not fully understood, genetic and environmental factors are thought to play an important role in its development (Professional Development, Part 1/3, 1994a).

Patient Classification--

Asthma symptoms and causes vary with each patient. However, it may be helpful to classify patients by severity as a guide to therapy. The National Asthma Education Program Expert Panel Guideline has categories of mild, moderate, and severe asthma (National Asthma Education Program, 1991).

Mild asthma.--generally has exacerbations no more than one or two times per week, few signs or symptoms (intermittent brief wheezes, cough, chest tightness, and dyspnea) between exacerbations, good exercise tolerance, and is awakened from sleep with symptoms no more than one to two times per month.

Moderate asthma.--is characterized by exacerbations of symptoms more than one to two times per week with occasional severe (life threatening) episodes requiring immediate expert emergency care less than three times per year.

Severe asthma.--symptoms occur nearly every day with frequent and often severe exacerbations requiring urgent care more than three times per year and hospitalization more than two times per year.

People can change categories but the goal is to shift to the mildest category (National Asthma Education Program, 1991; Reinke & Hoffman, 1992). In this study, most patients were categorized in their chart as being "mild", "moderate", or "severe". No attempt was made to recategorize patients due to this possible shifting between categories. If the patient was not categorized, the above classification system was used.

Metered-Dose Inhaler--

A device used to deposit medication into the tracheobronchial tree. It delivers the drug in a particle size of 1 to 5 millimeter, which allows it to travel to alveoli where it is needed. Drugs can be given directly and selectively to the lungs using small doses with rapid, predictable onset of action and minimal systemic side effects (Levin, 1991).

Spacer Devices--

An attachment to the MDI that extends the length from the MDI to the user's mouth by approximately six inches. The spacer device allows discharge of the drug in the MDI into a chamber where particles of medication are held in suspension for 3-5 seconds. During this time, the patient can inhale the drug. The spacer eliminates the rapid initial particle velocity, reducing the irritant properties of the aerosol and the tendency to cough. Deposition in the mouth and oropharynx is also decreased with the use of the space (Grossman, 1994).

B-agonist--

Have become the mainstay of treatment for asthma in the United States. The initial agents in the class were B_1-agonist (i.e. epinephrine and isoproterenol), whose effects on the heart produce increase ionotropic effects and tachycardia. The B_2-specific adrenergic agents (B_2-agonists) produce bronchodilation by stimulating the B_2 receptors in the lungs and have a decreased B_1 effect. They may also aid mucociliary clearance and have some effect on stabilizing mast cells (Levin, 1991).

Albuterol--

An approved B_2 agonist in all ages of children, including neonates, adolescents, and adults (Skidmore-Roth, 1996). The onset for albuterol by route of the MDI occurs as early as 1 minute, peak magnitude at 45 minutes, and duration as long as 6 hours. At 3 minutes, bronchodilation is at 80% peak and at 6 hours is at 50% peak (Weiss & Stein, 1993).

Pulmonary Function Tests--

Vital capacity.-the difference between total lung capacity and residual volume and is generated as a maximum inspiration followed by maximum expiration.

Forced vital capacity (FVC).-when vital capacity is obtained with as much forced effort as possible.

Forced expiratory volume in one second (FEV_1).-the volume of air expelled in the first second of a forced vital capacity maneuver (Mueller & Eigen, 1992). Healthy individuals are able to exhale more than three quarters of their FVC in the first second (Pfaff & Morgan, 1994).

Ratio of FEV_1 to FVC.- the portion of the FVC that is expired in one second

Forced expiratory flow from 25% to 75%. ($FEV_{25/75}$)-the average flow between those lung volumes and represents flows in the midportion of the vital capacity. Flows between 25% and 75% of the vital capacity are effort independent when a reasonable effort is made. Thus, training or additional effort cannot improve performance significantly.

Assumptions of the Study

1. It is assumed that each child is correctly diagnosed as having asthma. Each of the subjects are under the care of the same pediatric pulmonologist making it much more likely they were consistently diagnosed.

2. It must be assumed that the investigator administering the metered-dose-inhaler checklist was not only unbiased and objective in her measurement of knowledge but also accurate in her assessment of subjects' skills.

3. Likewise, it must be assumed that the pulmonary technician working with the children was consistent in his approach to each child. The forced expiratory flow from 25% to 75% ($FEV_{25/75}$) are effort independent though and should not reflect technician bias. It was attempted to use the same pulmonary technician for each child and this was achieved 95.8% of the time.

Limitations of the Study

1. The study design was implemented with two visits one to two weeks apart in order to ascertain if learning the proper use of the MDI resulted in improved PFTs. Environ-mental and overall well-being changes of the patient could make a difference on the outcome of the first and second visits. Changes in health status such as an upper respiratory infection or status unrelated to lung function (i.e. GI disturbance) could affect each child's PFT. Other factors could be stress related to change in parental control (as in a child of divorced parents). Two questions (Appendix C) pertaining to changes in health status were asked of the patient on the second visit in order to monitor for known changes, but there could be unknown status changes (i.e. unknown allergens) or mental stressors that were not voiced by the parent/child which could make a significant difference on performance.

2. The time limitation was the major determinate in keeping the study's numbers down and doing only a pilot study initially. A pilot study does not require enough subjects for significance, thus it must be kept in mind that significance was not obtained from the data.

3. The sample is homogenous. The subjects were all from the same military pediatric asthma clinic and thus were managed similarly but for varied amounts of time.

4. Each subject had their symptoms under relatively good control as evidenced by their baseline forced vital capacity (FVC). The degree at which bronchodilators have an affect on a subject with asthma under control will be less than for those subjects that have poor control of asthma. In other words, those with poor control have greater room for improvement on their FVC.

Summary

Since the MDI is the favored prescribed route of treatment for asthma and is used for children over six years of age (National Asthma Education Program, 1991), it is imperative that the proper use of the MDI be studied in this younger population in order to ensure that medication is reaching the lungs for optimal effect. Children in a military setting have inconsistencies in their care due to the mobility of both the patient and provider, and, thus require consistency in asthma education including proper use of the MDI. With proper education, the child can become more involved in his/her care and become more independent and self-confident in self-medicating with the MDI. Orem's concepts of self-care in the nursing process assisted the investigator in focusing on patient education.

CHAPTER TWO

Review of Literature

Throughout the readings, asthma is stated as being a problem of increasing concern. Of growing concern is the increase in asthma morbidity and mortality. From 1980 to 1987, the prevalence rate of asthma in the United States increased 29 percent, while death rates (asthma as the first-listed diagnosis) increased 31 percent (Anderson, 1991; Carswell et al., 1990; Levin, 1991; Professional Development, Part 1/3, 1994a; Schaffer, 1991; Tettersell, 1993). The morbidity and mortality related to asthma have not improved over the past 30 years, even though there has been an increased improvement in treatment and education (Huss, Salerno, & Huss, 1991). In the review of literature asthma is defined and an asthma classification of patients that is used in this pilot study is clarified. Medications and MDI use in asthma are addressed and pertinent studies are critiqued.

The clinician, physiologist, immunologist, and pathologist all have different perspectives of asthma. Thus, a widely accepted definition has been difficult to obtain. The generally agreed-on working definition of asthma recognized that asthma is a chronic respiratory disease characterized by smooth-muscle constriction of the airway that is reversible (but not completely in all patients), bronchial hyperresponsiveness, and an ongoing inflammatory process (American Board of Pediatrics, 1992; Janson-Bjerklie, 1993; National Asthma Education Program, 1991; Reinke & Hoffman, 1992; Schaffer, 1991).

Diagnosis

The criteria for diagnosis of asthma are recurrent episodes of wheezing relieved by bronchodilators and not attributed to a foreign body or infectious agents. These criteria have been established by the American Thoracic Society (National Asthma Education Program, 1991). Making a correct diagnosis of asthma is difficult. Symptoms can vary widely between individuals and it is important to remember that not all people with asthma

wheeze and all people who wheeze do not have asthma (Podell, 1992; Professional Development, Part 3/3, 1994b). According to McFadden & Gilbert (1992), nocturnal awakenings are such a common feature of asthma that their absence from the history leads experienced clinicians to doubt the diagnosis. It is rare for asthma to have an explosive onset. Typically, the initial symptoms are short-lived and intermittent; however, with time they can become more frequent and severe.

A thorough examination of the patient's medical and family history can help determine possible environmental triggers. The physical examination includes assessment of the upper respiratory tract, the chest, and the skin. The chest should be examined for evidence of hyperinflation and the quality of breath sounds. Again, wheezing is characteristic of asthma but not a reliable indicator of severity. Prolonged expiration is typical of airflow obstruction. Peak flow measurements are useful in following the course of asthma but are not sufficient to make the diagnosis. Spirometric analysis of pulmonary function is required for diagnosis (Janson-Bjerklie,1993). In asymptomatic patients, the physical examination may be normal, thus evidence of eczema, rhinitis, sinusitis, and polyps should be investigated (Pinkney-Atkinson, Irusen, & Rens, 1993).

Environmental Factors

Asthma is usually described as being extrinsic (allergic), intrinsic (idiopathic), or mixed (both types). Children more often have extrinsic asthma and intrinsic asthma is more likely to develop when the patient is 40 or older (Jess, 1992). The allergic reaction in the airways is significant for two reasons: (a) It can cause an immediate reaction with bronchial obstruction, and (b) it can precipitate a late bronchial obstructive reaction several hours after the initial exposure. The delayed bronchial response is associated with an increase in airway hyperresponsiveness to nonimmunologic stimuli and can persist for several weeks or more after a single allergen exposure (National Asthma Education Program, 1991). Indicated by the extensive list of asthma triggers listed in Table 1

(National Institute of Health, 1992), it is difficult to assess what triggers might have been affecting each child in this study at the time of each session.

Table 1
Asthma triggers

Allergies--

Foods	Pollens	Animals
nuts	flowers	rabbits
chocolate	trees	cats
eggs	grasses	dogs
orange juice	hay	hamsters
fish	ragweed	gerbils
milk		chickens
peanut butter		birds

Mold spores

Feather pillows
down comforters

Irritants--

Household products	Dusts
vapors from cleaning solvents	cloth upholstered furniture
paint	draperies
paint thinner	brooms
liquid chlorine bleach	dusters
sprays from furniture polish	dirty filters on hot air furnaces/air units
starch	
cleaners	On the Job
room deodorizers	dust
spray deodorants	vapors
perfumes	fumes from wood products
hair sprays	flour
talcum powder	cereals/grains
scented cosmetics	coffee/tea
	papain
	metals
	cotton/flax/hemp
	mold from decaying hay

Weather	Air Pollution	Emotions
blasts of cold air	traffic jams	fear
excessive humidity	parking jams	anger
changes in seasons	smoke-filled rooms	frustration
		laughing hard
Exercise	Smoke	crying
wheezing after overexertion	primary or secondary	coughing
	from cigarettes, cigars, or pipes	

Infections	Nighttime
colds	lying down
other viruses	tiredness
bronchitis	accumulating mucus
tonsillitis	
sore throat	

Medication

Medications are a major part of the treatment for asthma but vary with each patient. The National Asthma Education Program (1991) regime is to start the mild asthmatic on a *B*-agonist, two puffs by MDI every four to six hours as needed for symptom relief. Albuterol is the preferred B_2-agonist in children because it causes the least amount of side effects. If the episodes increase to moderate severity, an anti-inflammatory agent (e.g., cromolyn) or sustained release theophylline is added to achieve relief. If symptoms are not controlled with these, it may be necessary to add inhaled corticosteroids.

Bronchodilators are vital in the treatment of acute asthma attacks because they act quickly, but when a patient increases the use of an inhaled bronchodilator each day, this indicates poor control and therapy needs to be reviewed (Pinkney-Atkinson & Bateman, 1994). In the past few years, B_2-agonists have been reviewed for causing life-threatening episodes of asthma from their overuse (McFadden & Gilbert, 1992). However, the analysis of the data is not conclusive and inhaled B_2-agonists are still considered the first line of treatment for acute episodes and prevention of exercise induced asthma (Bechler-Karsch, 1994). Paradoxical responses are extremely rare. Only 126 instances were reported through 1988 in association with the use of 25 million metered-dose inhalers (McFadden & Gilbert, 1992).

Route of Administration

The MDI has emerged as the primary device for the outpatient treatment of asthma with inhaled bronchodilators, corticosteriods, and cromolyn sodium (Grossman, 1994). It delivers the drug in a particle size of 1 to 5 micrograms, which allows it to travel to the alveoli where it is needed (Levin, 1991). Proper use requires proficiency in a relatively complex technique and delivers 10 to 15% of the actuated dose to the airways if used properly (Thompson, et al., 1994). If steroid and bronchodilator are both prescribed, the

bronchodilator is used first to open the airways prior to the steroid administration (Braman & Kaemmerien, 1990).

Children less than six years of age will often need a spacer with the MDI. A spacer or holding chamber is a device that attaches to a MDI and holds the medicine in its chamber long enough for the patient to inhale the medicine in one or two slow deep breaths. With the use of a spacer, the medication is less likely to hit the pharynx and decrease the total drug delivered (National Asthma Education Program, 1991).

Pulmonary Function Tests

Physiologic measures are thought to be the most precise and objective methods used to obtain data. The data are measured at the interval or ratio level of measurement which allows the use of advanced statistical techniques (DeKeyser & Pugh, 1991). The National Asthma Education Program (1991) emphasizes the importance of formal pulmonary function testing in obtaining objective documentation of reversible airway obstruction. Pulmonary function test results in children are as reproducible as in adults. Clinically, pulmonary function values can be used to distinguish "normal" from "abnormal" or to examine a patient's function over time (Miller, 1987). The four pulmonary tests that are of interest done at this clinic are the forced vital capacity (FVC), forced expiratory volume in one second (FEV_1), ratio of FEV_1 to FVC, and the forced expiratory flow from 25% to 75% ($FEV_{25/75}$).

Vital capacity is the difference between total lung capacity and residual volume and is generated as a maximum inspiration followed by maximum expiration. When done with as much forced effort as possible, a forced vital capacity is obtained. The FEV_1 is the volume of air expelled in the first second of a forced vital capacity maneuver (Mueller & Eigen, 1992). Healthy individuals are able to exhale more than three quarters of their FVC in the first second (Pfaff & Morgan, 1994). The forced expiratory flow between 25% and 75% ($FEF_{25\%-75\%}$) of vital capacity is expressed as the average flow between those lung volumes and represents flows in the midportion of the vital capacity. Flows

between 25% and 75% of the vital capacity are effort independent when a reasonable effort is made. Thus, training or additional effort cannot improve performance significantly (Mueller & Eigen, 1992).

Usually patients with asthma have reduced forced expiratory volumes and flow rates. An airway obstruction is traditionally considered to be reversible if the patient's forced expiratory volume in one second increases by at least 15 percent after two puffs of a B_2-adrenergic agonist. In cases in which the spirometric measurements are normal, the diagnosis can be established by a finding of heightened airway responsiveness to histamine, methacholine, or isocapnic hyperventilation of cold air (McFadden & Gilbert, 1992).

Studies Pertaining to MDI Use

Most studies evaluating the proper use of MDIs are conducted on an adult population. A study by Larsen, et al., (1994) evaluated MDIs on a population of 501 outpatients ranging in age from 16 to 85 years of age and conducted at 12 sites throughout the U.S. The age ranges were not broken into age brackets thus the results were not specific to age but did state there was no difference in errors made by patient gender, patient age, or the medical specialty that treated the patient's pulmonary disease. A pilot study was conducted prior to their study in which 12 patients with asthma demonstrated their MDI techniques. In that trial, 83% of the patients made at least one error. Fifty-eight percent of the patients had difficulty with timing, primarily due to actuating the canister either too early or too late in the inspiratory cycle. Patients in the larger study were excluded if they routinely used a spacer device with their MDI or if they had received any instruction about the proper use of MDIs within one month of study entry. All patients were required to be experienced MDI users, having MDI use at least five times weekly for a minimum of one year before the study. To ensure that the patients used the MDI as they normally would, they were informed that the MDIs, rather than the individuals, were being evaluated.

In this study, 89.2% (determined by a liberal method of analysis) and 77.5% (by conservative method) of the patients made at least one error. There was no difference in errors made stratified by patient gender, patient age, or the medical specialty that treated the patient's pulmonary disease. The two most common errors made by patients were failure to breathe out fully prior to actuation of the inhaler and not actuating the canister at the start of inhalation.

Two observers were used to evaluate the MDI technique and each patient used the MDI twice at each site. Of the five observer pairs, observer 1 and 2 evaluated 40 patients and had the lowest percent agreement, with 67.5% agreement in observation 1. Observer pair 1 and 6 evaluated 141 patients and had the highest percent agreement for task 6 (firing canister at start of inhalation), with 85% agreement in observation 1 and 90% agreement in observation 2. Observers did not evaluate patient MDI use the same. Thus the results of the findings were not only dependent upon the patient but also the observer.

Another study of interest is the documented misuse of MDIs by medical personnel. This research conducted by Hanania, Wittman, Kesten, and Chapman (1994) was conducted in Canada and directed at respiratory therapists (RT), registered nurses (RN), and medical physicians (MD) (30 each). The RT's percent mean knowledge score of 67% was significantly higher than those achieved by RNs (39%) or MDs (48%). It was concluded from this study that many medical personnel responsible for monitoring and instructing patients in optimal inhaler use lack skills themselves. It is imperative that the health care provider giving information on MDI technique be skilled and knowledgeable in its use.

Another method of evaluating proper MDI use is by radiotracer technique. A study (Newman, Woodman, Clarke, & Sackner, 1988) used such a method. Patterns of deposition obtained by patients' usual techniques with the metered-dose inhaler were compared with those by correct MDI technique, and with those by InspirEase, a spacer device. Deposition of aerosol was assessed by placing Teflon particles labelled with ^{9om}Tc

inside a placebo cansiter, and inhaling maneuvers were monitored by respiratory inductive plethysography. Nine of the ten patients had imperfect technique with the MDI, the most prevalent errors being rapid inhalation and failure to hold their breath adequately. With patients' usual MDI techniques, 6.5 ± 1.2 percent of the dose reached the lungs. This was increased to 11.2 ± 1.3 percent with correct technique.

Asthma Education

In 1992 a pilot study was undertaken in Great Britain to determine whether the Asthma Education Center was improving patients' knowledge of their disease, and more importantly, to see if the patients made the correct management decisions. Reynolds and Ward (1994) examined the behavior of 45 patients with a mixed age group (14-60 years) over four months. Over this period patients monitored their asthma symptoms, peak flow, and medication, and filled in two questionnaires, one prior to education and one three months post-education. Reynolds and Ward reported results that showed there was an increase in the correct use of medication, an increase in recognition of asthma symptoms, and a reduction in symptoms and anxiety level. Of interest, the peak flow rate was increased from a score of 238.5 to 287.7 ($p<0.05$). Environmental variables between the two testings were not addressed. Perhaps the gain in knowledge to improve patient's control of his/her asthma also improves patient's overall well-being.

In contrast, another study investigating the attributes of asthma education concluded that patient compliance with drug therapy did not improve with education. Patient knowledge of asthma and treatment and compliance levels were assessed among 100 moderate to severe asthmatics recruited from a general practice in Great Britain. Age ranged from 14 years to over 50 years of age. Young adults were considered 14 years to 29 years and made up 21% of the sample. With the use of posttest questionnaires, it was discovered that 39% of patients admitted taking their asthma treatment as prescribed. The level of patient knowledge had no significant effect on compliance to drug therapy. The highest compliers were respondents who reported never receiving an explanation about

the condition. However, the level of patient knowledge appears to influence a patient's ability to manage an asthma attack. The study concluded that health professionals must look at other means of improving patient compliance rather than education in isolation (Tettersell, 1993).

The Workshop in Asthma Self-Management reviewed the data from a variety of educational methods. Most used didactic teaching and discussion groups, others developed written material, and at least one program utilized interactive computers. Self-management does not mean self-treatment but results in patients or parents accepting more responsibility for their care. Those who have participated in such courses did not overtreat at home or delay seeking appropriate medical care according to the workshop. An effective self-management program does not consist of a passive transfer of information but involves active participation (Howell, Flaim, & Lung, 1992).

Moe et al., (1992) researched one of these self-management programs in a childhood population. The effectiveness of a modified "Open Airways Program" developed by the National Heart, Lung, and Blood Institute was investigated. Seventy-four children ages 4 to 14 years and their families were randomized into one of seven classes as part of a larger study of pediatric asthma management. The medication session was the most popular session. Parents' confidence in understanding and managing their children's asthma rose from a preclass mean of 2.7 to a postclass mean of 4.2 ($p<0.001$, based on paired t test). When discussing medication, they used placebo inhalers to make sure the children knew how to use their inhalers properly. A weakness of this study was the lack of any information on the tool used to access proper MDI use.

Asthma camps for children can be a valuable source for critiquing educational programs. For the past 19 years, the American Lung Association of Florida has sponsored a camp for children with asthma who are unable to attend a camp without medical supervision. A pediatric pulmonary team of nurses, pharmacists, and social workers developed an asthma education program for presentation to children with asthma, ages 7

to 11 years. The team believed that in a camp setting, the educational programs needed to be fun and paced fast enough to hold the childrens' interest. Puppet shows lasting 15 minutes were followed by 45 minutes of games and arts and crafts activities that reinforced the content of the puppet show. Informal evaluation methods of observation and feedback indicated that children's knowledge of asthma and asthma management increased. The authors acknowledged that a scientific approach to evaluating efficacy would be necessary to validate the curriculum. No mention was made of improvement in pulmonary function with gained knowledge or an increase in compliance due to gained knowledge (Capen, Dedlow, Robillard, Fuller, & Fuller, 1994).

Educational methods reviewed clarified the need for an active rather than passive method of teaching as quoted by an educator.

> Current research recognizes that students do not receive or copy input from teachers, but instead actively mediate it by trying to make sense of it and to relate it to what they already know (or think they know) about a topic. Thus, students develop new knowledge through a process of active construction. (Brothy, 1992, p. 40)

Summary

The above literature concludes that asthma carries a high morbidity and mortality rate. If proper MDI technique can make a difference in the morbidity and mortality rate, it needs to be addressed. Studies are needed to ascertain if children are administering their MDIs properly, and if not, a teaching method is needed that will result in higher proper administration. As suggested by the literature, not only is education important, but a self-treatment plan which empowers the patient to be in control is needed for patient compliance. This pilot study implemented a one-on-one teaching plan to teach proper MDI use. Again, self-care is defined by Orem (1991) as "the practice of activities that individuals personally initiate and perform on their own behalf in maintaining life, health and well being". This definition requires active participation in order for performance to

take place. Specifically in this study, the subject had to actively use the MDI until correct use was achieved. Learning was reinforced, if needed, through repetition in order to score well on the performance posttest. Not only was the MDI performance scored, but actual pulmonary function was scored relative to MDI technique. The methodology used to implement a one-on-one teaching plan to teach proper MDI use and the measurement of performance and pulmonary function outcomes are covered in the following chapter.

CHAPTER THREE

Methodology

Introduction

The MDI has emerged as the primary device for the oupatient treatment of asthma. Medications (i.e., bronchodilators and anti-inflammatory drugs) can be deposited per aerosol directly into the lungs using small doses with a rapid, predictable onset of action with minimal systemic side effect (Levin,1991). Successful aerosol therapy generally depends on a typically small percentage (10 percent) of the drug dose delivered to the lungs from the MDI in the most ideal situation (Grossman, 1994). Proper use of the MDI includes inhaler technique, patient compliance, and appropriate dosage (Reardon & Bragdon, 1993). Inhaler technique in a young population (8 to 12 years of age) was the focus of this pilot study. Twelve subjects were evaluated using their MDI prior to teaching and after teaching. The one-on-one metered-dose inhaler teaching plan was the intervention. Frequency analysis was obtained on this data along with a descriptive analysis of each of the eight skills on the MDI use checklist. Testing was conducted on two days one to two weeks apart. Baseline pulmonary function tests were conducted each day and posttesting occurred after each MDI use with a bronchodilator. Paired t-tests were used to analyze the pulmonary function tests.

In this chapter, the subjects, site, and demography are described. Issues of protection of human subjects follow. The actual procedure for testing is delineated in a step by step method for ease of duplication. Operational definitions of the metered-dose inhaler teaching tool and the pulmonary function test utilized in this pilot study are clarified and the implementation of the metered-dose inhaler teaching plan is described. The research design is described briefly.

Obtaining Subjects

Parents of patients between the ages of 6 to 18 from a large military pediatric asthma clinic were contacted per telephone by the principal investigator. No

randomization was used in choosing patients, and all patients with workable telephones from an available list of patients seen in the last six months were contacted. These patients were diagnosed with mild, moderate, or severe asthma. They were told that a study to research techniques to teach skills and knowledge to children with asthma was to be conducted, and if interested, an appointment was made for the first visit. Upon arrival for the first clinic visit for the study, the parent was given a consent form (Appendix D) which explained the procedure and possible risks involved. Questions were answered at this time by the primary investigator. The research study was not explained in full until the first visit due to the possibility of parents/guardians intervening and teaching the child proper use of the MDI prior to testing which would damage the data results. Parents and children could freely decline to enter into the study and/or could withdraw at any time.

Study Participants

A convenience sample of children aged 6 to 18 years were recruited from a large military medical center. Criteria for inclusion in the study included:

1. A diagnosis by the pediatric pulmonologist as having asthma and categorized as mild, moderate, or severe.
2. Asthma was managed by the use of a bronchodilator metered-dose inhaler.
3. No other diagnosed major illness (i.e., congenital heart defects, diabetes, convulsive disorders, hyperthyroidism, or rheumatoid arthritis).

If, on the day of testing, the subject had a temperature elevation over 100.4 degrees F. or a pulse greater than 120, or cold symptoms that would affect performance on pulmonary function test, the subject was rescheduled.

The pretest and posttest study visits were timed such that patients did not have to wait long after arrival to begin testing, thus decreasing the likelihood of irritability in patient and/or parent. Patients were scheduled one hour apart in their visits to decrease the time of overlap and waiting. Posttest appointments were scheduled one to two weeks after the pretest and occurred within an hour of the pretest appointment in order to

decrease the variability in pulmonary function tests, since patients usually achieve improved results later in the day (National Asthma Education Program, 1991).

The Site

The convenience sample was obtained from a military pediatric asthma clinic that has a case load of 400 patients with a diagnosis of asthma. A pediatric pulmonologist is responsible for the asthma clinic which is normally open two days a week and has a monthly census of approximately 50. Patients may have been recently transferred from an acute care clinic or other provider source. The pediatric pulmonologist conducts visits that average 30 minutes per patient and does most of the teaching along with a registered nurse who manages calls and concerns of patients. Patient age varies from newborn to 21 years of age.

Patient Questionnaire

A questionnaire (Appendix C) to ascertain the demographic characteristics as well as information specific to asthma was completed by the parent of each subject on the initial visit. The information obtained was as follows: age, sex, race, age when first diagnosed with asthma, date of last hospitalization due to asthma, number of hospitalizations in last year, number of ER visits in the last year, asthma medications prescribed, number of providers that treated subject's asthma in the last year, environmental factors that made asthma symptoms worse that day, and medication dose and time taken that day. The questionnaire was completed on the second visit by the parent and child answering the following three questions:

1. Were there any changes in health or activity since the last visit for this study? If so, what?

2. Were there any environmental factors that made asthma symptoms worse on that second visit?

3. What medication was taken that day and at what time?

The descriptive data in the following chapter will cover this information.

Protection of Human Rights

Approval for conduction of this study was obtained from the Scientific Review Committee and the Committee for the Protection of Human Subjects of the National Naval Medical Center, Bethesda, MD. on July, 1995. Recommendation of minor changes in the subject permission form was made and final written approval was received September, 1995. Although the subjects had to be identified in order to correlate the pretest and posttest results, confidentiality was maintained by using a coded number system to attach to each test. The possible risks or discomforts to the subject were addressed and approved by the Institutional Review Board as follows: The normal dose of the bronchodilator was used twice each visit with at least 20 minutes between each dose. Thus the side effects of nervousness, nausea, or increased heart rate that the patient might experience at home, could also occur while being tested. The heart rate was taken and recorded prior to each dose of bronchodilator. If the heart rate was over 120 beats per minute, the bronchodilator was not given. The heart rate was also taken and recorded after testing was completed at each visit. Each subject was not released unless the heart rate was within normal range for his/her age. If any new significant findings developed during the course of the research which could affect willingness of participant to continue in the study, patient and parent/guardian were informed. The subject and parent/guardian had the inconvenience of returning to the clinic one to two weeks from pretest to take the posttest. An explanation of the study was provided to the patient and guardian, and a consent (Appendix D) for voluntary participation was obtained prior to participation. Those choosing not to participate in the study were told they would not incur any penalty or loss of benefits to which they were already entitled. Subjects were free to ask questions or to withdraw from the project at any time.

Procedure

The procedure for this project involved two clinic visits lasting approximately one hour each.

On the first visit the subject:

1. Had a baseline pulmonary function test prior to testing.

2. Was tested on the proper use of the metered-dose inhaler using the normal prescribed two puffs of bronchodilator as used at home.

3. Had a pulmonary function test 10 minutes after the metered-dose inhaler test was completed and the bronchodilator was used.

4. Was taught the eight steps to use the metered-dose inhaler correctly by utilizing the eight steps of the metered-dose inhaler teaching plan and a demonstration MDI without medication.

5. After achieving a score of at least seven on the metered-dose inhaler test without medication (eight is perfect score), and a lapse of at least 20 minutes since the last dose of MDI bronchodilator, used the MDI with two puffs of bronchodilator and again was tested on its use according to the metered-dose inhaler checklist.

6. Had a pulmonary function test 10 minutes after MDI use.

The subject was scheduled for the second visit one to two weeks later and scheduled within one hour of the same time of the day of the first visit.

On the second visit the subject:

1. Had a baseline pulmonary function test prior to testing.

2. Was tested on the proper use of the metered-dose inhaler using his/her normal dose of two puffs of bronchodilator.

3. Had a pulmonary function test done 10 minutes after the bronchodilator was self-administered by the MDI..

4. After a lapse of 20 minutes since last dose of MDI bronchodilator, was tested on proper use of self-medication of a bronchodilator with the MDI.

5. Had a pulmonary function test done 10 minutes after the use of the MDI with bronchodilator.

Metered-Dose Inhaler Teaching Tool

The metered dose inhaler skills checklist (Appendix A) was developed by the National Institute of Health. The tool has eight criteria that are checked to assure proper use of MDI with or without the spacer. A score of one is given to each indicator answered "yes" and a zero for those answered "no". A total of eight signifies a perfect score. The tool has no copyright according to the National Institute of Health and no written agreement was needed for its use (National Asthma Education Program, 1991).

The first question of the checklist is, "Did the patient shake the inhaler (for several seconds) prior to use?" The drug in a metered dose inhaler is a suspension of particles in liquid propellant. The particles tend to float on the heavy chlorofluorocarbon; thus, the shaking of the canister before each actuation is vital. Failure to shake the canister will result in propellant without drug being delivered whether the canister is full or nearly empty (Simpson, 1993). The MDI facilitates the distribution of medication into the tracheobronchial tree by aerosolization.

The second question deals with the full exhalation prior to inhalation. A full exhalation to tidal volume will increase the depth of deposition (Reardon & Bragdon, 1993). The third question deals with the anatomical positioning. When the head is tilted back the greatest area is opened to allow the medication to go straight into the respiratory tract.

The fourth question deals with the method in which the inhaler is held. The hand position on the inhaler must be monitored closely and not only answered by "yes" or "no" but must include a description of how the child held the MDI. The method described is to hold the inhaler with the index or middle finger on top of the medication canister and the

thumb supporting the inhaler's bottom. This may be difficult for small hands and needs to be reviewed if children are consistently holding the cannister incorrectly.

The fifth question deals with the spacer when used. The spacer mouthpiece should be between the teeth, and the lips sealed around the tube. The spacer allows the fine aerosol with medication to have the high volume burst hit inside the spacer instead of the back of the pharynx and requires that the lips be closed around the spacer tube (National Asthma Education Program, 1991). The second part of question five deals with those who do not use the spacer. The closed mouth technique depicted in many drug inserts prevent the development of an airflow sufficient enough to capture the particles at peak flow, thus increasing pharyngeal deposition. Holding the MDI two fingerbreaths in front of the mouth reduces particle impact on the posterior pharynx, and improves drug delivery (Reardon & Bragdon, 1993).

Questions six and seven deal with the breathing technique. The inhalation breath should be slow at the time of inhaler discharge. Slower inspiratory flow rates lead to better peripheral airway deposition and holding the breath for 5 to 10 seconds after inhalation will lead to greater deposition in the alveoli (two times) before the particles are exhaled.

The last question deals with the time lapse between puffs. An interval of 1 to 3 minutes between successive puffs of *B*-agonists and 5 to 10 minutes before using other MDI medications are "probably adequate". Thus, bronchodilation occurs after the first puff allowing subsequent puffs to penetrate deeper. Since patients are normally prescribed bronchodilators, bronchodilators were the only medication used in this study, and the two puffs taken while demonstrating MDI use did not exceed the dose normally prescribed. Patients not prescribed bronchodilators were omitted from the study.

Pulmonary Function Test

The pulmonary technician working with the child subjects had technical training in working with children. The child held the mouthpiece between the teeth and a seal was

made by the lips. A nose clip was used on the child's nose. The child was coached and encouraged during expiration to help achieve a complete forced vital capacity, "pushing" as long as possible for at least three seconds. Three efforts within a 5% difference of each other helped assure the tester that reproducibility had been achieved.

Baseline pulmonary function tests were done initially upon each visit prior to administration of medication. Proper use of the MDI was tested by an eight question tool while the child took his/her normal dose of bronchodilator drug, and then the pulmonary function tests of the subject was measured. The proper technique was then taught by utilizing a one-on-one teaching technique using the MDI checklist tool until scores of use were improved to at least a score of seven. The teaching tool was given to the child and parent for continued use at home. The posttests were conducted one to two weeks later to again measure proper MDI technique. Again the child's normal dose of bronchodilator was taken while MDI use technique was tested and pulmonary function obtained afterwards.

Assessment of reliability data for physical measures that yield continuous data should include the following: mean, minimal, and maximal differences; standard deviation of the net differences; and technical error of measurement (Engstrom, 1988). Requirements for instrumentation have been standardized within the past ten years by the American College of Chest Physicians and the American Thoracic Society. For this study there was not a comparison of results among the subjects but only a comparison between pretest and posttest for all subjects in order to ascertain if improved MDI use resulted in improved PFTs.

A total of six PFTs for each child were obtained. In asymptomatic children, the peak flow rate (PFR) and forced expiratory volume in one second (FEV_1) may be normal while flow rates at lower lung volumes are reduced. The reserve volume (RV) is usually increased (due to the trapped air in the alveoli). As obstruction increases, the PFR and FEV_1 decrease, and the RV is further increased with a reduction in forced volume capacity

(FVC). With the use of a bronchodilator, there should be an improvement of lung capacity (Miller, 1987). It is recognized that there are environmental factors which effect pulmonary function tests which could not be controlled.

The Intervention: Metered-Dose Inhaler Teaching Plan

The metered-dose inhaler teaching plan (Appendix B) was conducted with each subject after the inhaler skills checklist and pulmonary function pretests had been conducted. A teaching tool developed from the inhaler skills checklist was used to teach each subject the criteria of the tool in order to properly use the MDI. The eight points were rearranged in order as to what actually occurred in sequence. Each of the eight points were demonstrated. Deficiencies were identified by utilizing the Metered-Dose Inhaler Skills Checklist (Appendix A). Teaching was individually tailored to those deficiencies and then the patient retested the same day in order to improve scores and validate that learning took place. A score of no less than seven was considered passing. The rater, a registered nurse with 23 years experience, obtained on the job training from two medical professionals that worked extensively with the National Asthma Education Program. No study was found in which MDI use was tested solely on a pediatric population.

Research Design

Data collection was started in August, 1995 just prior to childhood asthma peak season of September, and data collection was completed near the end of asthma peak season in November. This was busy school entry time for parents and children.

An interrupted time-series pretest-posttest design was used in this quasi-experimental pilot study. Time-series analyses have some advantages over other quasi-experimental designs. Repeated pretest observations can assess trends in maturation before the treatment. The repeated pretest observations also allow measures of trends in scores before the treatment. According to Burns & Grove (1993), there are particular problems in the time-series designs. "Record-keeping procedures and definitions of constructs used for data collection tend to change over time. Thus, maintaining

consistency can be a problem." Environmental allergens, emotional changes, and health status changes were the main outside factors that could not be controlled and were hard to measure. See Table 2 for descriptive outline of the design.

Table 2
Simple Interrupted Time Series

Measurement of dependent variables	Manipulation of independent variable	Measurement of dependent variables
PRETEST---------->	TREATMENT---------->	POST-TESTS

Experimental----->M(1)---->M(2)---->T----->M(3)----TIME----M(4)---->M(5)---->M(6)

M=Measurement of dependent variables
T=Treatment--Manipulation of the independent variable

SPSS for Windows was used in the analysis of data. Mean, mode, median, minimum, maximum, range, and standard deviation were used for the descriptive data. Paired samples included baseline PFTs between day one and day two, PFTs after MDI (#1) use day one and after MDI (#3) use day two, and lastly the paired-t tests of PFTs after MDI (#2) use day one and MDI (#4) use day two. The pretests measure the dependent variables of knowledge and pulmonary function; the treatment manipulates the independent variable by using one-on-one teaching; and the posttest measures the dependent variables of skill knowledge and pulmonary function after the one-on-one teaching. This design showed the current status and the effectiveness of a one-on-one teaching strategy.

The internal validity is the extent to which the findings reported in the study are a true reflection of reality, rather than being the result of the effects of extraneous variables. This study is examining causality, therefore it needs to be determined if the independent and dependent variables may be caused by an unmeasured, third variable. The first dependent variable is the score on the metered-dose inhaler skills checklist. The second

dependent variable of the pulmonary function test does have outside factors that may influence the results either negatively or positively. It was attempted to minimize these variables by decreasing the time between testing to only one to two weeks. Each patient was scheduled for the second visit within a two hour period same time of day as the first visit. Subjects were asked on the patient questionnaire of changes in status from the first visit, but this information was not tabulated into SPSS in any way.

Summary

The problem has been identified, the protection of human subjects addressed, and the procedure carried out as outlined above. A further description of the subjects enrolled, the data obtained from their metered-dose inhaler skills checklist, and the subjects' data from their pulmonary function tests will be analyzed further in the following chapter.

CHAPTER FOUR

Data Analysis

Introduction

Metered-dose inhalers are the primary route of administration of asthma medications and are used daily in the self-medication of asthma drugs by children as well as adults. The success of the MDI in treating lung disease depends chiefly on inhaler technique along with patient compliance, and appropriate dosage. Inhaler technique was the focus of this pilot study. Pretest and posttest results of proper MDI skills were measured with the intervention of a one-on-one teaching plan between the two tests. The results of the eight question metered-dose inhaler checklist test were pretested using descriptive statistics. Pretest and posttest measures also included pulmonary function tests in order to ascertain if proper use actually improved lung function.

Information obtained on each question of the metered-dose inhaler checklist was helpful in determining the specific problems of each child and also highlighted specific problems that may be of concern for most children. With this knowledge, teaching techniques can be directed to solve those problems. Each individual's pretest and posttest scores were first compiled to assess individual problems and then group scores were processed. This chapter is divided into three parts, the demographic description of the subjects, the descriptive statistics of the MDI skill testing, and the paired *t*-testings of the pulmonary function tests. Research questions and hypotheses are addressed within the relevant parts.

Characteristics of the Sample

In the general population, for those less than 10 years of age, the incidence of asthma in males outnumbers females. Once puberty is reached, the incidence is equal between the two genders. For adult onset asthma, the incidence changes once more with females outnumbering males (Asthma Statistics, 1992). Specific to this pilot study in the age group from 8 to 12 years of age, the sampling had a 2:1 male to female ratio. The

incidence of asthma is higher (5.3:4.7) in the general population for African Americans compared to Caucasians. In this pilot study the Caucasian subjects outnumbered the African American subjects 2:1.

Table 3
Demographics

Age	Gender	Race
Range: 8 to 12 years	66.7% male	66.7% Caucasian
Mean: 10.083 years	33.3% female	16.7% Caucasian/Asian
Mode: 9.0 years		16.7% Black

Classification of patients' severity into categories of mild, moderate, and severe seems to have little significance when subjects change categories due to improved status with treatment and are not reclassified in their chart. Perhaps of greater utility would be subjects with decreased PFTs (whether classified as mild, moderate, or severe) at the time of testing in order to ascertain changes in PFTs with proper use of the MDI.

Table 4
Onset and Severity of Asthma

Onset of Asthma (in years)	Classification of Severity
Range: 1 year to 8 years	Range: mild to severe on a scale of 1 to 5
Mean: 5 years	Mean: 2.75
Mode: 6 years	Mode: 2.0

One can assume that with an increase in emergency room (ER) visits and an increase in number of providers, there would be an increase of asthma severity. The one subject that had 12 providers in the last year was the patient with the most ER visits (10). Two other subjects had comparably poor results. The remaining nine subjects had from one to three providers and zero to three visits to the ER.

Table 5
Number of Providers and Emergency Room (ER) Visits in Last Year

Numger of Providers Treating Asthma	Number of ER Visits
Range: 1 to 12 providers Mean: 3.9 Mode: 1.0 SD: 4.7	Range: 0 to 10 per subject Mean: 2.2 visits Mode: No visits SD: 3.4

All of the subjects were prescribed albuterol inhalers but of varying frequency of dosage. Half were to use the medication only as needed, while the other subjects were to use it two or three times a day and also as needed.

Table 6
Medications

Medications	Frequency
Albuterol inhaler:	All subjects 2 puffs either bid, qid or prn.
Corticosteriod inhaler:	All subjects (91.67% beclamethazone or 8.33% triamcinolone)
Third asthma inhaler:	Three subjects (25%) were prescribed a third asthma inhaler of either salmeterol or cromolyn sodium

It was difficult to rate the changes in status from the first visit to the second on a scale due to varying differences of the changes and also due to the varying perception of each child. The changes varied from no changes (six subjects), better the second visit (one subject), to illnesses between the two visits that included mild cold, exacerbations of allergies, wheezing, or nausea and vomiting. One child from a separated home visited his mother in another state between the two visits and failed to take his medications with him but also had not taken them routinely all summer.

Data for Hypothesis One

Improved metered-dose inhaler technique will be obtained through a one-on-one individualized teaching plan.

The 12 subjects did improve their metered-dose inhaler technique after a one-on-one individualized teaching. It is assumed that the learning achieved was due mainly to the teaching intervention. Each question of the MDI Skills Checklist was analyzed in order to ascertain which skill was difficult for each child individually and as a group which skills seem to be difficult for children to master.

After the investigator taught the skill of shaking the canister prior to use, all subjects retained the skill throughout testing. See Table 7.

Table 7
Question One: Did the patient shake the inhaler prior to use?

Day One	Day Two
Pretest: 75%	Posttest Teaching 2: 100%
Posttest Teaching 1: 100%	Posttest Teaching 3: 100%

It is important to exhale fully in order to inhale to a greater depth the subsequent dose of bronchodilator. As noted in Table 8, the skill was learned during the teaching intervention, was sucessfully demonstrated immediately following the intervention but was not retained by all on the second visit until the skill was again reviewed.

Table 8
Question Two: Did the patient exhale fully prior to inhalation?

Day One	Day Two
Pretest: 58.3%	Posttest Teaching 2: 83.3%
Posttest Teaching 1: 100%	Posttest Teaching 3: 100%

Tilting the head to improve the angle for increased deposition of medication into the lungs scored the poorest of all skills prior to the intervention teaching. Perhaps this was one part of teaching proper MDI use in the clinic that was initially omitted. When the pediatric pulmonologist was told of this poor rating, he stated that he was not concerned with tilting the head in those who used a spacer due to the decreased force of the particles hitting the back of the pharynx.

Table 9
Question Three: Did the patient tilt back his or her head prior to inhalation?

Day One	Day Two
Pretest: 0%	Posttest Teaching 2: 91.65%
Posttest Teaching 1: 100%	Posttest Teaching 3: 100%

Dexterity in holding and handling the inhaler was not a problem even prior to teaching. Perfect scores were obtained throughout. The subjects' hands were large enough to hold the canister properly.

Table 10
Question Four: Was the inhaler held and discharged with the index or middle finger on top of the medication canister and the thumb supporting the inhaler's bottom?

Day One	Day Two
Pretest: 100%	Posttest Teaching 2: 100%
Posttest Teaching 1: 100%	Posttest Teaching 3: 100%

Several children stated they used the spacer but failed to bring it with them. Others stated they used a spacer but admitted to misplacing the spacer. A new, clean spacer was provided for all subjects who were accustomed to using a spacer. Only two subjects did not use a spacer.

Table 11

Question Five:

(If a spacer is used) Did the patient have his or her lips closed and the spacer tube between his or her teeth during discharge? (Ten patients routinely used spacers.)	(If a spacer is not used) Was the inhaler held 2 to 5 cm. from the patient's open mouth during discharge? (Two patients did not use spacer.)
Day One	Day One
Total: 58.3%[a] Pretest: 70%[b]	Pretest: (0:2) 0%[c]
Total: 75%[a] Posttest Teaching 1: 90%[b]	Posttest Teaching 1: (0:2) 0%[c]
Day Two	Day Two
Total: 83.3%[a] Posttest Teaching 2: 100%[b]	Posttest Teaching 2: 0%[c]
Total: 83.3%[a] Posttest Teaching 3: 90%[b]	Posttest Teaching 3: 50%[c]
[a]n=12	[b]n=10 [c]n=2

Breathing slowly after discharge is not a factor in those patients who use spacers due to the fact that the spacer holds the medication in suspense. See Table 12.

Table 12

Question Six: Did the patient inhale slowly and deeply after inhaler discharge?

Day One	Day Two
Pretest: 83.3%	Posttest Teaching 2: 83.3%
Posttest Teaching 2: 100%	Posttest Teaching 3: 91.65%

All subjects held their breath at least five seconds after inhalation breath prior to teaching and retained this skill throughout. See Table 13

Table 13
Question Seven:
Did the patient hold his or her breath for 5 to 10 seconds after inhalation?

Day One	Day Two
Pretest: 100%	Posttest Teaching 2: 100%
Posttest Teaching 1: 100%	Posttest Teaching 3: 100%

On the pretest the subjects initially scored poorly on the eighth skill. As noted in Table 14, the posttest scores indicated attainment and retention of this skill following the teaching intervention. The second puff of bronchodilator will have more effect if the dose is taken after the first dose has had time to open the airways. Initially only two subjects waited the appropriate time between puffs. To teach the minimum time interval between puffs the primary investigator played games such as hangman, tic-tac-toe and dot to dot with the subject in between puffs and had subjects indicate when the two minutes time had lapsed.

Table 14
Question Eight: How long did the patient wait before taking a second puff? Check "yes" if the patient waited two or more minutes; otherwise, check "no".

Day One	Day Two
Pretest: 16.3%	Posttest 2: 91.65%
Posttest Teaching 1: 83.3%	Posttest 3: 100%

Prior to the intervention of one-on-one teaching of proper MDI use, the skill level of all the subjects ranged from 37% to 87% with a mean ratin of 61%. After the teaching intervention, two subjects missed one skill each while the other ten scored 100%. One week later, five subjects retained the 100% accuracy while six subjects missed one skill out of eight, and the twelfth subject missed three out of the eight skills. Nine subjects

scored 100% accuracy on the third posttest score, with the remaining three subjects each missing one of the skills. The total MDI scores are summarized in Table 15.

Table 15
Data of MDI Scores from Each Subject

	Pretest	Posttest #1	Posttest #2	Posttest #3
Subject 1:	75%	100%	100%	100%
Subject 2:	75%	100%	100%	100%
Subject 3:	50%	100%	87%	100%
Subject 4:	62%	100%	100%	100%
Subject 5:	50%	100%	87%	87%
Subject 6:	75%	100%	100%	100%
Subject 7:	37%	87%	87%	100%
Subject 8:	62%	100%	87%	100%
Subject 9:	37%	87%	87%	87%
Subject 10:	75%	100%	87%	100%
Subject 11:	87%	100%	100%	87%
Subject 12	50%	100%	75%	100%

Data for Hypothesis Two

Pulmonary function results will improve with improved metered-dose technique.

The results of the pulmonary function tests proved to be interesting and confusing. Even though all subjects had at least a 10% improvement in metered-dose technique, they did not improve on pulmonary function significantly or consistently with use of the bronchodilator by MDI. The percentages for FVC, FEV_1, and $FEF_{(25-75\%)}$ for each child's baseline, pre-teaching MDI use, and post MDI on the first day and a repeat of those tests on the second visit are found in the Appendex E. Although the purpose of this study was not to look at individual PFT results, it was noted that five of the subjects baseline $FEF_{(25-75\%)}$ are greater than 100% both the first and second day.

There were nine paired t-test results compiled from the information in Appendex E and tabulated by SPSS. The percent of predicted for each subject was entered into SPSS for comparison rather than the actual readings of each child due to the fact that the actual

is based upon that child's sex, age height, weight, and race. The percentages of predicted pulmonary function of each child is a comparable factor. The p value had to be less than 0.05 to be of statistical significance. As known from the beginning of this pilot study, there was not enough power with this small number to achieve statistically significant results.

Three tests of the pulmonary function were analyzed in the t-test; the forced vital capacity (FVC), the forced expiratory volume in one second (FEV_1), and the flows between 25% and 75% of the vital capacity ($FEV_{25/75}$) which is the most effort independent. The three paired t results for each of these three pulmonary function tests are as follows:

1. Baseline day one : Baseline day two
2. Pre-teaching of the MDI #1 day one : Post MDI #3 use day two
3. Post MDI #2 day one : Post MDI #4 day two

The mean results of each pulmonary function test is in the second column of Table 16; the difference of the mean between the matched pairs is in the third column; the t-value of the matched pairs is in the fourth column; and the p value for each the matched pairs is in the last column.

Table 16
PFTs Paired t-test Results

Matched Pairs	Mean	Paired Differences Mean	t-value	p
Baseline FVC Day One	93.25			
Baseline FVC Day Two	93.83	-.58	-.63	.54
FVC Pre-teaching MDI	93.58			
FVC Post MDI #3	93.83	-.25	-.16	.87
FVC Post MDI #2	93.67			
FVC Post MDI #4	93.08	.58	.22	.83
Baseline FEV_1 Day One	92.42			
Baseline FEV_1 Day Two	92.17	.25	.25	.81
FEV_1 Pre-teaching MDI	95.25			
FEV_1 Post MDI #3	95.33	-.08	-.05	.96
FEV_1 Post MDI #2	96.42			
FEV_1 Post MDI #4	95.50	.92	.35	.74
Baseline $FEF_{(25-75\%)}$ Day One	94.83			
Baseline $FEF_{(25-75\%)}$ Day Two	91.50	3.33	1.32	.21
$FEF_{(25-75\%)}$ Pre-teaching MDI	108.08			
$FEF_{(25-75\%)}$ Post MDI #3	102.92	5.17	1.45	.18
$FEF_{(25-75\%)}$ Post MDI #2	107.42			
$FEF_{(25-75\%)}$ Post MDI #4	106.83	.58	.09	.93

This chapter covered the demography of the sample population, the descriptive statistics of the eight parts of the MDI skills checklist, and the analyses from the paired t-tests of the pulmonary function test. The next chapter will summarize the results of the data. Due to the small sample size of a pilot study, it is difficult to draw conclusions concerning the hypothesis but recommendations can be made to improve the design of further study.

CHAPTER FIVE

Conclusions and Implications

Summary of the Study

Metered-dose inhalers are the mainstay of treatment in the outpatient setting for asthma in children as well as adults (Grossman, 1994). Approximately ten percent of the aerosol from the MDI reaches the lungs when the MDI is used correctly. Proper use requires proficiency in a relatively complex technique (Thompson, et al. 1994). Studies of the adult population have shown that only 45% to 50% of adult asthma patients utilize the MDI correctly (Reardon & Bragdon, 1993). This pilot study examined the effectiveness of a teaching tool for proper MDI use in a young population (8 to 12 years). Pretest and posttest scores of MDI use were obtained along with baseline pulmonary function tests (PFT), and posttest pulmonary function test after each MDI use.

This final chapter will present the findings from the data analysis in four parts as follows:

1. The demographic findings of the subjects
2. Problems encountered along the way
3. The conclusion of the eight part MDI teaching checklist along with recomendations for each of the eight parts.
4. Conclusion from the results of the pulmonary function paired t-test along with recommendations.

Demography

Age, Gender, and Race

In the general population, for those less than 10 years of age, the incidence of asthma in males outnumber females. Once puberty is reached, the incidence is equal between the two genders. For adult onset asthma, the incidence changes once more with females outnumbering males (Asthma Statistics, 1992). Specific to this pilot study in the age group from 8 to 12 years of age, the sampling had a 2:1 male to female ratio. The

incidence of asthma is higher (5.3:4.7) in the general population for African Americans compared to Caucasians. In this pilot study the Caucasian subjects outnumbered the African American subjects 2:1. Due to the small sample size and possibly due to the demographics of this specific clinic, this sample is not reflective of the general population by race.

Age of Asthma Onset

Onset of asthma ranged from as early as one year of age to eight years of age. No comparison was made between the severity and age of onset or with the coping skills and knowledge level of the child that had been exposed to asthma education for many years as compared to the child that was diagnosed only a year prior. Too many variables are present to make that comparison. Several of the children seemed to experience difficulty learning the content/skills of the teaching intervention. However, such difficulty was not noted in the subjects' charts.

Classification by Severity

Due to patients moving between the three different categories of mild, moderate, and severe and not being recategorized, it was difficult to place much meaning on the category. Often children change according to seasonal patterns and are not categorized again. Treatment is given according to symptoms and not to categories even though the literature seemed to make a broad statement concerning treatment according to category (National Asthma Education Program, 1991). Even though a child was categorized as moderate to severe, with treatment, the child's status was much improved. What dictated each child's status at the time of testing was the baseline PFTs that day.

Number of Providers Treating Asthma in the Last Year

The number of providers treating asthma in the last year was increased for those who made more frequent visits to the ER due to the very fact that they were being seen in the ER and saw a different provider each time they were seen in the ER. The overall status of a patient for the past year could be assumed to be poor if those numbers were

increased. When patients are managing their asthma properly, the number of ER visits should decrease. Patients with increased visits to the ER should be sought out for asthma education and support.

Medications and Dosing

All subjects were prescribed albuterol but in varying doses. All subjects were prescribed a corticosteriod inhaler and 25% (3 subjects) were prescribed a third asthma inhaler. Severity of asthma was increased with the increase in number of medications, but the control of asthma was also increased. Corticosteriod inhalers as preventers of inflammation have been the mainstay of treatment in only the last few years. In this clinic which is managed by a pediatric pulmonologist, most children with asthma are prescribed a corticosteriod inhaler. If subjects were chosen from acute care clinics or ERs, the rate of corticosteriod inhaler use would probably not be as high. Thus, the management of those not on a corticosteriod inhaler would probably not be as well controlled.

Problems Encountered

The children and parents varied in their response as to how often and when the medication was taken. The children were often left to self-medicate without parental control. The age that each child takes on this responsibility varies with each child, but may be forced upon the child before he/she is properly trained and ready. Of more concern was the lack of parental and child knowledge of the appropriate use of medications. One parent thought salmeterol was the same medication as albuterol when in fact its onset of action is 5-15 minutes, peak is later (4 hours), and the duration is much longer (12 hours). Salmeterol is a bronchodilator but should not be used as a reliever for acute symptoms. Although the purpose of this pilot study was not to focus on medication knowledge or parental knowledge, the need certainly was acknowledged.

Another problem encountered along the way was the fact that some children medicated with their bronchodilator prior to testing that day. This was a neccessity for some due to the fact that some subjects were consistently seen in the morning and some

consistently seen in the afternoon. All subjects scheduled for morning appointments were told to hold their medication that morning until seen (unless symptomatic), but some forgot and medicated which probably changed their baseline PFTs results. Further control of time of day is needed. Perhaps if the study was done at an asthma camp where testing and dosing would be in control, this inconsistency in dosing would be alleviated.

Another inconsistency that occurred was the use of spacers. In this pediatric asthma clinic, patients are encouraged to use spacers and in fact 10 of the 12 subjects routinely used one with their MDI. For consistency of testing, it would be better to either have all subjects with or without a spacer.

The two testing times were purposely scheduled one to two weeks apart in order to decrease the chances of environmental changes. In order to evaluate the staying power of learning that took place, testing should be done again in six months to a year later (prior to moving or dropping from the clinic).

A pulmonology technician that was determined to be well trained in working with children was assigned to the study. This brought about consistency to the PFTs for the majority of the children with one exception when reassignment occurred before the last patient returned for the second visit. In a larger study, the pulmonology technician would have to be committed for a longer time period.

The primary investigator was the only observer for the MDI checklist. Using only one observer can bring consistency to the observation, but brings the possibility of being consistently wrong. An observation of this investigator was the fact that she was more organized in her evaluations after she had completed two to three observations in the setting where testing took place. It is recommended that prior to a large study, a trial of three patients be used at the testing site with the assigned pulmonology technician and primary investigator being evaluated by a specialist in the field of childhood asthma.

Originally 14 subjects volunteered to participate in the study but two subjects had to be dropped from the study. One subject, a 15 year old female, had difficulty in

performing the pulmonary function tests. The pulmonary technician tried to repeat the test over a twenty minute period, but the subject was unable to exhale over a three second time period. Thus, reliable PFTs were unattainable and the subject was dropped from the study after proper use of the MDI was taught. The pulmonary technician stated this seemed to be a problem with young teenage girls concerned with the way they looked while performing PFTs with a clip on their nose. The second subject dropped from the study was a ten year old female. When instructed to use her MDI the first time in order to be pretested for proper MDI use, she proceeded to rapidly use six puffs of albuterol even though the chart stated she was prescribed two puffs. Due to the extra dosing of bronchodilator she was eliminated from the study, but for teaching purposes she was taught proper use of the MDI along with proper dosing. She also returned for a second visit to reinforce the teaching.

Conclusions and Recommendations for MDI Checklist

Hypothesis One: Improved metered-dose inhaler technique will be obtained through a one-on-one individualized teaching plan.

The 12 subjects did improve their metered-dose inhaler technique by at least ten percent after one-on-one individualized MDI teaching. It must be kept in mind that there was only a one to two week lapse in time between testing. To test retainment of knowledge a six month to one year lapse in time is needed. Each of the eight skills will be summarized.

Question One: Did the patient shake the inhaler prior to use?

This skill is important whether a spacer is used or not due to the importance for the drug to float on the heavy chlorofluorocarbon. The pretest results on this skill was at 75% and maintained at 100% post intervention.

Question Two: Did the patient exhale fully prior to inhalation?

A full exhalation to tidal volume will increase the depth of medication deposition into the lungs. This skill is needed whether the spacer is used or not. Only 58% met this

requirement prior to teaching but 100% performance rate was achieved on the second post test each day.

Question Three: Did the patient tilt back his or her head prior to inhalation?

This anatomical position may decreases the amount of medication that hits the pharynx. With the spacer, the force of the medication coming out is contained in the spacer rather than hitting the pharynx. This is of less importance when the spacer is used, but is still a contributing factor because overall posture is improved when the child tilts his/her head back. When posture is improved, the lung capacity improves. This skill gained the most improvement from 0% pretest to 100% posttest.

Question Four: Was the inhaler held and discharged with the index or middle finger on top of the medication canister and the thumb supporting the inhaler's bottom?

This skill had 100% positive results pretesting and posttesting thus needed the least amount of teaching. At this age level (8 to 12 years), dexterity of hand use did not seem to be a problem. It probably is a problem in the elderly or those with arthritis or other debilitating diseases, but with healthy children it may not be a problem.

Question Five: (If a spacer is used) Did the patient have his or her lips closed and the spacer tube between his or her teeth during discharge.

With a spacer this skill was easier to perfect. Pretest score was at 70% with spacer use, and posttest score was at 90% for the group. Further studies with spacer use are needed to ascertain what time period can lapse before the particles in the spacer tube can no longer be inhaled. Since so many of the subjects used spacers, the MDI skills checklist needs to be evaluated more in depth for spacer use.

If a spacer is not used: Was the inhaler held 2 to 5 cm. from the patient's open mouth during discharge?

Two subjects did not use a spacer. This skill seemed harder to learn due to the fact they were taught the closed mouth technique. Both open and closed mouth techniques are taught in medication inserts even though the literature states there is less

deposition of medication on the post pharynx with the open mouth technique. For study purposes, it is desirable to have subjects use the same method. Only one of the two were able to master the skill and that was on the last posttest. Whether mastery was retained is unknown.

Question Six: Did the patient inhale slowly and deeply at time of inhaler discharge?

Timing is a particularly difficult skill to achieve according to the literature (Reardon & Bragdon, 1993), but with spacer use may not be a necessity. Nonetheless, this group scored at least 83% throughout testing.

Question Seven: Did the patient hold his or her breath for 5 to 10 seconds after inhalation?

Holding the breath after inhalation will lead to greater deposition in the alveoli (two times) before the particles are exhaled (Reardon & Bragdon, 1993). This skill achieved 100% both pre and posttesting. Thus teaching only reinforced what was already achieved.

Question Eight: How long did the patient wait before taking a second puff?

Bronchodilation occurs one to three minutes after use. Thus subsequent dosing will reach deeper into the alveoli when a time lapse between puffs is obtained. This skill improved from a preteaching score of 16% to postteaching score of 100% on the last post test score. This skill should improve deposition whether or not a spacer is used.

Conclusions and Recommendations for PFT Paired t-tests

Hypothesis: Pulmonary function results will improve with improved metered-dose technique.

Even though all subjects improved MDI technique by at least ten percent, pulmonary function did not improve significantly or consistently with use of the bronchodilator MDI. It was a known in this pilot study from the beginning that there were

not enough available subjects during the designated data collection period to bring about statistical significance.

Another contributing factor may be that ten of the twelve subjects on the initial first day visit had baseline $FEF_{(25-75\%)}$ above the 80% range Thus, the subjects' pulmonary status were not compromised enough to cause improvement with a bronchodilator whether or not performed properly. Recommendation for further study would require the subjects to have a compromised pulmonary status requiring the need for MDI use. Perhaps if the study was done at an asthma camp there would be more control of subjects' dosing regime and testing could be done when a natural acute situation occurred rather than induce compromise. Other ways to cause compromize would be by histamine challenge, or a more natural challenge would be an exercise induced challenge.

There were subjects that seemed to have particular difficulty in learning proper MDI skills. These subjects initially scored lower on pretest MDI checklist. Of course, no aptitude test of any kind was obtained on the subjects. All children with asthma need asthma education initially and should be reviewed at each visit. Perhaps children consistently scoring low on skills test need to be singled out for intensive one-on-one training and periodically evaluated for retainment of those skills. This might bring about a larger yield in improvement rather than intensive training for all children.

Information gained from the two subjects omitted from the study was thought provoking and invaluable. Further research to evaluate adolescents, and in particular female adolescents, would be helpful in order to motivate these individuals to comply to proper self-care treatments.

Summary

The goals of all therapeutic interventions in the case of a chronic illness should be to minimize the biologic manifestations, complications, and progression of the illness, and to enable the patient to function as independently as possible. The care should not be directed at a cure, which may be unattainable, but at optimal achievable function (Carswell

et al. 1990). The National Asthma Education Program (1991) established a program with guidelines to teach both children and adults management programs. The program stresses the importance of providers establishing a partnership with each patient. This program emphasizes the importance of demonstrating such devices as the inhaler, nebulizer and peak flow meter, and then having the patient demonstrate to the clinician or provider the proper use on subsequent visits. In summary, this pilot study utilized Orem's self-care concept to implement a one-on-one teaching plan to educate the child in the proper use of the MDI. This teaching required active learning on the part of the child. This knowledge, if put into action, could empower the child with asthma to become more self-reliant and in control of this chronic disease.

TABLE OF APPENDICES

Appendix A

Metered-Dose Inhaler Skills Checklist

1. Did the patient shake the inhaler (for several seconds) prior to use?
   Yes No

2. Did the patient exhale fully prior to inhalation?
   Yes No

3. Did the patient tilt back his or her head prior to inhalation?
   Yes No

4. Was the inhaler held and discharged with the index or middle finger on top of the medication canister and the thumb supporting the inhaler's bottom?
   Yes No If no, describe how the inhaler was held.

5. (IF A SPACER IS USED) Did the patient have his or her lips closed and the spacer tube between his or her teeth during discharge?
   Yes No

   (IF A SPACER IS NOT USED) Was the inhaler held 2 to 5 cm. (1 to 2 in.) from the patient's open mouth during discharge?
   Yes No

6. Did the patient inhale slowly and deeply at time of inhaler discharge?
   Yes No

7. Did the patient hold his or her breath for 5 to10 seconds after inhalation?
   Yes No

8. How long did the patient wait before taking a second puff? CHECK YES IF THE PATIENT WAITED 2 OR MORE MINUTES; OTHERWISE, CHECK NO.
   Yes No

INHALER SKILLS SCORE (#Yes)_____
(If score is 6 or less, repeat all instructions with patient; if 7, correct the missed step only)

9. Did parent/guardian assist child with MDI?
   Yes No

10. Does the parent/guardian usually assist child with MDI?

    Yes No

Appendix B

Metered-Dose Inhaler Teaching Plan

1. Shake the inhaler for several seconds; otherwise, the medication does not mix with the liquid propellant and the medication does not come out correctly.

2. Tilt the head back slightly. (This opens the airway space so the medication has a straighter path to the lungs.)

3. The inhaler is to be held with the index or middle finger on top of the medication canister and the thumb supporting the inhaler's bottom.

4. If the spacer is to be used, the lips should seal around the tube and the end of the tube should be beyond the teeth. If the inhaler is used without the spacer, it should be held 2 to 5 cm. (1 to 2 in.) from the mouth with the mouth open.

5. Blow out (exhale) a big breath (a full exhalation to tidal volume will increase the depth of deposition).

6. Activate the inhaler by pushing on top of the inhaler while breathing in slowly.

7. Hold your breath at full inspiration for 5 to 10 seconds.

8. ASK THE PATIENT & /OR PARENT: If you were really using your inhaler, how long would you wait before taking a second puff? The right answer is 2 or more minutes. (Make a game of timing 2 minutes.)

Appendix C

Patient Questionnaire

1. Date of birth_____Last 4 of Sponsors SS#_____
2. Sex _____
3. Race_____
4. Age when first diagnosed with asthma_____
5. Date of last hospitalization due to asthma_____

   Number of hospitalizations in last year_____
6. Number of ER visits in last year_____
7. Present asthma medications used_____

   _____
8. Approximate date when Metered-dose inhaler (MDI) first prescribed_____
9. Was use of the MDI in your opinion demonstrated or taught well when first prescribed?_____

_____

10. Number of providers that have treated your asthma in last year_____
11. Are there any environmental factors that are making asthma symptoms worse at present?_____
12 What medications have been taken today and at what time?

_____

To be answered at second visit:

13. Are there any changes in health or activity since the last visit for this study?

    If so, list:
14. Are there any environmental factors that are making asthma symptoms worse today?
15. What medication have been taken today and at what time:

Appendix D

Date: Pg 1 of 4

NATIONAL NAVAL MEDICAL CENTER
BETHESDA, MARYLAND

Consent for Voluntary Participation in a Clinical Investigation Study

1. My child_____, have been asked to voluntarily participate in a research project entitled, "Proper Use of the Metered-Dose Inhaler in Children Utilizing a One-on-One Teaching Plan" being conducted at the National Naval Medical Center, Bethesda, Maryland.

2. The purpose of this research project is to:
   -examine the current technique of metered-dose inhaler usage in children 6 to 18 years of age in a military facility.

   -measure the effectiveness of a one-on-one teaching plan to improve metered-dose inhaler technique use for those children who demonstrate incorrect MDI technique.

   -identify specific problems of metered-dose inhaler technique in children.

3. I understand my child's participation in this research project will be for a period of two weeks.

4. The procedure for this project involves: Two clinic visits lasting approximately one hour.
   On the first visit the subject will:
   -be tested on the proper use of the metered-dose inhaler using the normal prescribed two puffs of bronchodilator as used at home.

   -have a pulmonary function test done 10 minutes after the metered-dose inhaler test was completed and the bronchodilator was used.

   -be taught the eight steps to use the metered-dose inhaler correctly by utilizing the eight steps of the metered-dose inhaler teaching plan and a demonstration of the MDI without medication.

   -after achieving a score of at least seven on the metered-dose inhaler checklist (eight is a perfect score), and a lapse of at least 20 minutes since the last dose of the MDI bronchodilator, use the MDI with two puffs of bronchodilator and again be tested on it's use according to the metered-dose inhaler checklist.

-have a pulmonary function test 10 minutes after the proper use of the MDI.

The subject will be scheduled for the second visit one to two weeks later and scheduled within one hour the same time of the day of the first visit.

On the second visit the subject will:
-be tested on the proper use of the metered-dose inhaler using his/her normal dose of two puffs of bronchodilator.

-have a pulmonary function test done 10 minutes after the bronchodilator was self-administered by the MDI.

-after a lapse of 20 minutes since the last dose of MDI bronchodilator, again be tested on proper use of self-medication of a bronchodilator with the MDI.

-again have a pulmonary function test 10 minutes after use of the MDI with bronchodilator.

5. Specifically, I am aware that the experimental part of this research is the controlled setting in which the metered-dose inhaler test with the normally prescribed bronchodilator and the pulmonary function test are conducted. The reason for the testing is to ascertain if proper use of the metered-dose inhaler will improve the lung capacity and if one-on-one teaching helps the patient to use the MDI correctly.

6. A total of at least 12 subjects are expected to participate in this project.

7. The risks or discomforts which are possible are as follows:
The normal dose of the bronchodilator will be used when the metered-dose test is given (once each visit), and thus the side effects of nervousness, nausea, or increased heart rate that the patient might experience at home, may also incur while being tested.

I understand and accept these risks.
_____Guardian Initials

8. I understand that the research may or may not help my child personally but that the results may help the investigator learn about the proper use of the metered-dose inhaler (MDI) in a younger population and therefore find ways that will assist others to use the MDI properly.

9. The alternate treatment, should I decline enrollment into this study, has been explained as follows: My child will be taught proper use of the MDI, but will not be officially tested on the proper use of the MDI. A pulmonary function test may or may not be done depending on the physician's decision to test.

10. If any new significant findings develop during the course of the research which may effect my or my child's willingness to participate further,they will be explained to me.

11. In all publications and presentations resulting from this research project, my child's anonymity will be protected to the maximum extent possible; although, I realize that authorized Navy Medical Department personnel may have access to my research file in order to verify that my rights have been safeguarded.

12. If my child suffers any physical injury as a result of my participation in this study, immediate medical treatment is available at the National Naval Medical Center, Bethesda, Maryland. I understand that although no compensation is available, any injury as a result of my child's participation will be evaluated and treated in keeping with the benefits or care to which he/she is entitled under applicable regulations.

13. If I have any questions regarding this research project, I may contact Dr. John McQueston at (301) 295-4902 or Maj. Janet Bourne at (301) 946-6151. If I have any questions regarding my child's rights as an individual while participating in a research project at the National Naval Medical Center, Bethesda, I can contact one of the Research Administrators, Clinical Investigation Department, at (301) 295-2275. She will answer my questions or refer me to a member of the Committee for the Protection of Human Subjects for further information. If I believe I have been injured as a result of this project I may call the legal office (301) 295-2215.

14. I understand that my child's participation in this project is voluntary and that my refusal to participate will involve no penalty or loss of benefits to which he/she is entitled under applicable regulations. If I choose for my child to participate, I am free to ask questions or to withdraw my child from the project at any time. If I should decide to withdraw him/her from the research project, I will notify Maj. Janet Bourne at (301) 946-6151 to ensure an orderly termination process. My withdrawal will involve no loss of benefits to which I am entitled.

Guardian Initials_____

I certify that I have received a copy of this consent form.
Parent/Guardian Initial_____

_____	_____
Subject typed Name-Status-	Witness's Signature & Date
	_____
	Witness' typed Name-Rank-Title SSN
_____	_____
Parent/Guardian Signature & Date	Investigator Signature & Date
_____	_____
Relationship to Patient/Subject	Investigator typed Name -Rank-SSN

PRIVACY ACT STATEMENT

1. Authority. 5 USC 301

2. Purpose. Medical research information will be collected to enhance basic medical knowledge, or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury or performance impairment.

3. Use. Medical research information will be used for statistical analysis and reports by the Departments of the Navy and Defense, and other U.S. Government agencies, provided this use is compatible with the purpose for which the information was collected. Use of the information may be granted to non-Government agencies or individuals by the Chief, Bureau of Medicine and Surgery in accordance with the provisions of the Freedom of Information Act.

4. Disclosure. I understand that all information contained in this Consent Statement or derived from the experiment described herein will be retained permanently at National Naval Medical Center, Bethesda, Maryland and salient portions thereof may be entered into my health record. I voluntarily agree to its disclosure to agencies or individuals identified in the preceding paragraph and I have been informed that failure to agree to such disclosure may negate the purposes for which the experiment was conducted.

_____ _____

Subject/Guardian Signature Signature of Witness

_____

Typed Name, Grade or Rank

_____

Date of birth of child

Appendix E
Percent of each Subject's PFTs

	Baseline Day 1	Pre-teaching MDI	Post MDI #2	Baseline Day 2	Post MDI #3	Post MDI #4
Subject #1						
FVC	94%	97%	96%	95%	97%	94%
FEV_1	99%	104%	104%	100%	104%	100%
$FEF_{(25\%-75\%)}$	116%	133%	134%	117%	130%	130%
Subject #2						
FVC	91%	90%	90%	93%	94%	95%
FEV_1	91%	93%	94%	95%	97%	99%
$FEF_{(25-75\%)}$	117%	129%	128%	125%	127%	138%
Subject #3						
FVC	99%	96%	99%	102%	100%	103%
FEV_1	95%	96%	100%	100%	99%	102%
$FEF_{(25-75\%)}$	85%	94%	101%	92%	99%	97%
Subject #4						
FVC	94%	98%	95%	98%	97%	99%
FEV_1	91%	100%	99%	91%	95%	94%
$FEF_{(25-75\%)}$	92%	122%	118%	74%	93%	75%
Subject #5						
FVC	88%	93%	96%	90%	98%	100%
FEV_1	76%	84%	92%	69%	90%	96%
$FEF_{(25-75\%)}$	51%	68%	86%	36%	73%	89%
Subject #6						
FVC	111%	112%	113%	115%	120%	115%
FEV_1	108%	114%	108%	108%	122%	115%
$FEF_{(25-75\%)}$	101%	117%	97%	94%	114%	98%
Subject #7						
FVC	111%	113%	112%	110%	113%	113%
FEV_1	113%	111%	120%	112%	115%	118%
$FEF_{(25-75\%)}$	113%	101%	126%	107%	104%	124%
Subject #8						
FVC	104%	102%	99%	100%	98%	103%
FEV_1	106%	107%	106%	103%	102%	107%
$FEF_{(25-75\%)}$	110%	123%	127%	104%	110%	120%
Subject #9						
FVC	69%	61%	67%	64%	66%	68%
FEV_1	69%	67%	68%	67%	68%	75%
$FEF_{(25-75\%)}$	84%	112%	72%	87%	106%	125%
Subject #10						
FVC	102%	99%	99%	102%	89%	70%
FEV_1	101%	101%	102%	104%	92%	75%
$FEF_{(25-75\%)}$	94%	106%	96%	102%	83%	79%
Subject #11						
FVC	79%	81%	81%	83%	80%	83%
FEV_1	79%	82%	82%	80%	82%	85%
$FEF_{(25-75\%)}$	78%	92%	83%	72%	81%	92%
Subject #12						
FVC	77%	81%	77%	74%	72%	74%
FEV_1	81%	84%	82%	77%	78%	80%
$FEF_{(25-75\%)}$	97%	100%	121%	88%	115%	115%

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